



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,075	02/19/2004	Sean D. Monahan	Mirus.030.16.6	4417

25032 7590 06/28/2005

MIRUS CORPORATION
505 SOUTH ROSA RD
MADISON, WI 53719

EXAMINER

CHONG, KIMBERLY

ART UNIT	PAPER NUMBER
----------	--------------

1635

DATE MAILED: 06/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/782,075

Applicant(s)

MONAHAN ET AL.

Examiner

Kimberly Chong

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 April 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 14-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 01/10/05, 03/03/05
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Art Unit: 1635

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of group I, claims 1-13, in the reply filed on 04/26/2005 is acknowledged. Claims 14-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Status of the Application

Claims 1-13 are pending and currently under examination. Claims 14-20 are withdrawn from further consideration.

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

In the instant application, the priority date granted to claim 11 is 02/19/2004. The instant claim does not receive the benefit of the earlier filing date of the following: Application Nos. 60/448,789 and 60/455,724 because claim 11 of the instant application is not supported by the specification and claims of the previously mentioned parent applications. The parent applications disclose the modified RNA can consist of dsRNA, ribozyme or siRNA. The parent applications do not disclose the RNA can be microRNA. If Applicant believes support is in the parent applications, Applicant should point, with particularity, to where such support is to be found.

Art Unit: 1635

Therefore, the priority date granted to claim 11 is 02/19/2004, the filing date of the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claims are drawn to a "...composition for delivering an RNA to a mammalian cell comprising a post-synthetically modified RNA." It is unclear what is delivering the RNA to the cell. A composition cannot contain one only one component, namely a modified RNA, and be a composition capable of delivering an RNA to a cell.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Art Unit: 1635

Claims 1-2, 5, 10 and 12-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Bennett et al. (US Patent No. 6,156,786).

Claim 1 is drawn to a post synthetically modified RNA. Claims 2 and 5 recite the modified RNA consist of a functional group, as listed in claim 5, attached to the RNA. Claim 10 limits claim 1 by reciting the composition comprises a transfection agent. Claims 12 and 13 limit claim 1 by reciting an *in vitro* or *in vivo* mammalian cell and the modified RNA is more resistant to nucleases.

Bennett et al. disclose a post synthetically modified RNA (see column 5, lines 39-42 and column 7, lines 37-40). Bennett et al. further disclose modified RNA consists of a functional group (see column 9, lines 3-30) and the modified RNA can be introduced into mammalian cells using a transfection agent (see Example 9).

Thus, Bennett et al. anticipates claims 1-2, 5, 10 and 12-13 of the instant application.

Claims 1-2, 4-9 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Goldsborough (WO 01/94626).

Claim 1 is drawn to a post synthetically modified RNA. Claims 2 and 4-5 limit claim 1 by reciting the modified RNA consists of a functional group attached to the RNA and the functional group is linked to a ribose 2'-hydroxyl RNA. Claim 6 limits claim 4 by reciting the modified RNA is modified at a single ribose 2'-hydroxyl, more than one but not all of the ribose 2'-hydroxyls or all of the ribose 2'-hydroxyls. Claims 7-9 and 13 further limit claim 1 by reciting the modified RNA consists of a silylated RNA, an acylated RNA, an alkylated RNA and the modified RNA is more resistant to nucleases than an unmodified RNA.

Goldsborough disclose an RNA molecule that is modified at the 2'-hydroxyl position (see page 21) and wherein the RNA consists of a functional group (see page 58). Goldsborough further disclose the RNA can consist of a silylated RNA (see page 25), an acylated RNA (see page 20) or an alkylated RNA (see page 21). Goldsborough disclose the modified RNA consists of a functional group attached to a ribose 2'-hydroxyl position (see page 41), the modified RNA has more than one, but not all of the ribose 2'-hydroxyl positions modified (see page 13) and the modified RNA are more resistant to nucleases (see Example 61).

Thus, Goldsborough anticipates claims 1-2, 4-9 and 13 of the instant application.

Claims 1, 2, 4, 10 and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Tuschl et al. (WO 02/44321).

Claim 1 is drawn to a post synthetically modified RNA. Claims 2 and 4 limit claim 1 by reciting the modified RNA consists of a functional group attached to the RNA and the functional group is linked to a ribose 2'-hydroxyl RNA. Claim 10 limits claim 2 by reciting the composition comprises a transfection agent and claim 12 limits claim 1 by reciting an *in vitro* or *in vivo* mammalian cell.

Tuschl et al. disclose a 2'-hydroxyl modified RNA wherein the modification comprises a functional group (see page 5 last paragraph to page 6 first paragraph). Tuschl et al. further disclose the modified RNA can be delivered via a transfection agent into mammalian cells *in vivo* or *in vitro* (see page 8, lines 1-18).

Thus, Tuschl et al. anticipates claims 1, 2, 4, 10 and 12 of the instant application.

Art Unit: 1635

Claims 1, 2, 4 and 11 are rejected under 35 U.S.C. 102(e) as being anticipated by Tuschl et al. (US 2005/0059005).

Claim 1 is drawn to a post synthetically modified RNA. Claims 2 and 4 limit claim 1 by reciting the modified RNA consists of a functional group attached to the RNA and the functional group is linked to a ribose 2'-hydroxyl RNA. Claim 11 limits claim 1 by reciting the RNA is a siRNA or a microRNA.

Tuschl et al. disclose a 2'-hydroxyl modified RNA wherein the modification comprises a functional group (see paragraph 0016 and 0017). Tuschl et al. further disclose the RNA consists of a microRNA or siRNA.

Thus, Tuschl et al. anticipates claims 1, 2, 4 and 11 of the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-9 and 13 are rejected under 35 U.S.C. 103(a) as being obvious over Goldsborough (WO 01/94626) in view of Monahan et al (US Patent No. 6,630,351).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the

Art Unit: 1635

inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Claim 1 is drawn to a post synthetically modified RNA. Claims 2 -5 limit claim 1 by reciting the modified RNA consists of a functional group attached to the RNA, the functional group is linked to the RNA via a labile bond and the functional group is linked to a ribose 2'-hydroxyl RNA. Claim 6 limits claim 4 by reciting the modified RNA is modified at a single ribose 2'-hydroxyl, more than one but not all of the ribose 2'-hydroxyls or all of the ribose 2'-hydroxyls. Claims 7-9 and 13 further limit claim 1 by reciting the modified RNA consists of a silylated RNA, an acylated RNA, an alkylated RNA and the modified RNA is more resistant to nucleases than an unmodified RNA.

Goldsborough disclose an RNA molecule that is modified at the 2'-hydroxyl position (see page 21) and wherein the RNA consists of a functional group (see page 58). Goldsborough further disclose the RNA can consist of a silylated RNA (see page 25) or an acylated RNA (see page 20). Goldsborough disclose the modified RNA consists of a functional group attached to a ribose 2'-hydroxyl position (see page 41), the modified RNA has more than one, but not all of

Art Unit: 1635

the ribose 2-hydroxyl positions modified (see page 13) and the modified RNA are more resistant to nucleases (see Example 61). Goldsborough et al. do not teach the functional group of the RNA is attached via a labile bond.

Monahan et al. disclose labile bonds that attach functional groups, such as membrane active compounds, to RNA.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to attach a functional group to an RNA using a labile bond, as taught by Monahan et al., to the modified RNA, as taught by Goldsborough et al.

One would have been motivated to attach a functional group to modified RNA via a labile bond because attaching a functional group to a nucleic acid using a labile bond allows for delivery of a compound in a less active form that is selectively broken and becomes active under specific desired conditions.

Finally, one would have a reasonable expectation of success because Monahan et al. specifically teach attachment of functional groups using labile bonds (see columns 39 and 40).

Thus in the absence of evidence to the contrary, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly Chong whose telephone number is 571-272-3111. The examiner can normally be reached Monday thru Friday between 7-4 pm.


Art Unit: 1635

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached at 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Kimberly Chong
Examiner
Art Unit 1635



ANDREW WANG
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600